Remarks

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-5 were pending in this application when last examined.

Claims 1-3 were examined on the merits and rejected.

Claims 4-5 were withdrawn as non-elected subject matter.

Claims 1-3 are amended. Support for the recited conditions can be found on page 3, lines 13-24, of the specification as filed. Support for "1 μM eosinophil cationic protein" can be found on page 15, lines 4 and 12, page 16, lines 3 and 22, page 17, line 25, page 18, line 9 and pages 20, lines 22-23, of the specification as filed.

Claims 6-19 are newly added. Support for these claims can be found on page 3, lines 13-24, in the Examples on pages 14-21 and in the claims in the specification as filed. Support for "1 μM eosinophil cationic protein" can be found as indicated above.

No new matter has been added.

In item 12 on page 1 of the Office Action, the Examiner partially acknowledged the claim for foreign priority, as well as receipt of the certified priority documents from the International Bureau. However, the Examiner failed to check the appropriate box in 12(a-c). Applicants respectfully request the Examiner to fully acknowledge the claim for foreign priority in the next Office Action.

II. ENABLEMENT REJECTION

In item 3 on pages 2-4 of the Office Action, claims 1-3 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is only enabling for compositions

comprising ECF that promote fibroblast proliferation, actin cytoskeleton formation, and survival of PC12 cells growing in serum-free media, and not enabling for therapeutic compositions for diseases caused by a failure in the survival, proliferation and/or differentiation of a cell, such as heart disease, bone disease or neurodegenerative disease.

Applicants note that claims 1-3 have been amended to recite diseases caused by specific conditions. Applicants further note that these conditions are enabled by page 3, lines 16-21 and the Examples on pages 14-21 of the specification as filed. Applicants therefore submit that these claims, as amended, are enabled.

Applicants further note that the Office, on pages 3-4, noted that some art literature found ECP to be a neurotoxin while the present application shows ECP to promote neuronal survival. Applicants note that all basic substances including ECP show cytotoxic at high concentrations. In particular, when eosinophil are activated, basic proteins such as ECP, MBP, EDN and EPO, which are present in basic granules, are discharged and as their concentrations increase they exhibits cytotoxicity. However, the invention as claimed is directed towards the newly discovered fact that low concentrations of ECP have a stimulatory effect on cell differentiation.

Further, to address the discrepancies noted by the Examiner, Applicants have amended the rejected claims to require only low concentrations of ECP. Applicants note that the molecular weight of ECP is about 15.5 kDa. Thus, one μM is equal to 15.5 μg/ml and 100 ng/ml is equal to 6.5 nM. In the examples given in the specification, the maximum amount of ECP administered for activation is 1 μM.

Thus, Applicants submit that ECP exhibits similar functionality as cytoskeleton factors and growth factors in that it causes activation at very low concentrations.

Thus, Applicants note that the specification enables claims 1-3 as amended. Applicants further note that the newly discovered activities noted in the specification for ECP do not contradict the knowledge in the art because the claims as amended recite a low concentration of ECP. Applicants therefore suggest that the rejection of claims 1-3 under 35 U.S.C. 112, first

paragraph, as applied to the amended claims, is untenable and should be withdrawn.

III. ANTICIPATION REJECTION

In item 5 on pages 4-5 of the Office Action, claims 1-3 were rejected under 35 U.S.C. 102(b) as anticipated by WO 01/85766. Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that claims 1-3 have been amended to recite "up to 1 μM eosinophil cationic protein". On the other hand, WO 01/85766 discloses an assay (as discussed by the Examiner on page 4 of the Office Action) with 20 μg/ml/well. As noted above, since 1 μM is about 15.5 μg/ml, this reference fails to teach this newly added limitation. Therefore, WO 01/85766 fails to teach or suggest each and every element of the claimed invention and this rejection, as applied to the amended claims, is untenable and should be withdrawn.

Applicants further note that the invention of the amended claims is based on the new discovery that low concentrations of ECP stimulate cell differentiation. Furthermore, Applicants submit that, until now, no research reports existed on purified genetically modified ECP and its effect on activation of cell differentiation. For example, in Patella et al. (cited by the Examiner) purified ECP from natural sources is used at .3-3 μM and activation of less than 20% is indicated.

Thus, the cited art fails to teach compositions for the treatment of the cited diseases at low concentrations of ECP. Thus, Applicants submit that this rejection is untenable and should be withdrawn.

IV. CONCLUSIONS

In view of the foregoing amendments and remarks, the present applications is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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